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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/832,393	04/10/2001	Frank Robert Witter	55693	8536

21874 7590 09/22/2004

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EXAMINER

WINAKUR, ERIC FRANK

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 09/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/832,393

Applicant(s)

WITTER, FRANK ROBERT

Examiner

Eric F Winakur

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 5-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 5-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

1. Claims 21, 28, and 37 are objected to because of the following informalities: With regard to claim 21, it appears that the claim should depend from claim 20 to provide basis for the phrase "the recess". With regard to claim 28, it appears that the claim should depend from claim 27 to provide basis for the phrase "the blood extraction device". With regard to claim 37, it appears that the term "configures" (lines 8 and 10) should read "configured". Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 25, 26, and 36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. With regard to claim 25, the phrase "the shielding member" (lines 10 and 11) lacks antecedent basis. With regard to claim 26, it appears that the term "the" should be inserted before "shielding device" (line 7) and "of" should be inserted after "devoid" (line 7). With regard to claim 36, the phrase "the body portion" (lines 3 - 4) lacks antecedent basis.

Claim Rejections - 35 USC § 102

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. The rejection of claims 1, 2, and 5 - 37 under 35 U.S.C. 102(b) as being anticipated by Anderson (5,372,581 - cited by Applicant) is hereby maintained.

6. The rejection of claims 19 - 24, 26, and 36 under 35 U.S.C. 102(b) as being anticipated by Foss is hereby maintained.

Response to Arguments

7. Applicant's arguments filed 16 June 2004 have been fully considered but they are not persuasive. With regard to the rejections based on the Anderson reference, Applicant argues the apparatus and method claims separately, and Examiner will respond to the separate arguments. With regard to the apparatus claims (19 - 24, 25, 26 - 32, 36, and 37), Applicant alleges that 1) the claimed structure differs from that of Anderson in that the claimed shielding member/device does not include any type of fastening mechanism or is devoid of mechanisms for fastening, 2) the structure of Anderson requires clamping mechanisms, and 3) due to this difference, Anderson cannot anticipate the claims. All of Applicant's claimed devices include a "cradle member" having certain distinguishing features: a) a portion configured to be held in a hand of a user, b) a portion configured to receive a body portion or umbilical cord, and c) there is no fastening mechanism in the device. As detailed in the prior Office Action, Anderson's structure shown in Figure 6, (elements 21, 22, 36, 23, 29) meet these limitations. Since Anderson discloses the claimed structure, it is considered to meet the claim limitations even if the final assembled structure or method of use differs from Applicant's preferred embodiment.

Further, the "cradle member" is described as being configured so that a digit of a user's hand secures and stabilizes the body portion/ umbilical cord. Although Applicant argues extensively on this point, this is merely an intended use of the device that does not result in a structural limitation of the device that patentably distinguishes over the prior art.

Applicant's conclusion that a rejection of the apparatus claims under 37 CFR 102 by Anderson must include consideration and comparison of the intended use of Applicant's device and that of Anderson, and that Anderson's teachings regarding use of clamping structures must be considered to be part an "equivalent" structure for purposes of the comparison is inapt. As detailed above, Anderson discloses each and every structure set forth in the claims. Consistent with the portions of the MPEP that Applicant quotes, Anderson teaches each and every claimed element and the elements are arranged as required by the claims. Thus, Anderson meets the claimed apparatus structure, and the rejections of claims 19 - 32, 35, and 36 are hereby maintained.

Applicant's arguments regarding the method claims (1, 2, 5 - 15, 16 - 18, 34, and 35) essentially rest on interpretation of the phrase "stabilizing the body portion within the shield member" or "stabilizing the umbilical cord within the shield member" and comparison with Anderson's disclosed use of clamps to "restrict" the umbilical cord. Analysis and comparison of the claimed subject matter and that of Anderson relies on 1) comparison of the terms "stabilizing" and "restricting" and 2) determination of the meaning of the phrase "within the shield member". With regard to the first aspect, Applicant appears to argue that the two terms are essentially similar, and that if an

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element is restrained it is stabilized. Examiner has reviewed Applicant's disclosure, and has not found any particular definitions attached to these terms. A review of a dictionary (Webster's New World Dictionary, Third College Edition) shows that stabilizing refers to making something not easily moveable, while restricting is to keep within certain limits. It is apparent that these terms are not as close in meaning as Applicant implies in the arguments. While the clamps of Anderson restrict movement (longitudinal) of the body portion, they still allow movement (radial/rotational) of the body portion (cord) within the shield member.

Further, the stabilizing "within the shield member" step requires that the stabilizing inside the limits of the shield member be done solely by a digit of a user's hand, as "within" refers to inside the limits of. The figures and descriptions of Anderson clearly show that there are not any structures inside the limits of the shield member, and that only a subject's digits are used to achieve the stabilizing.

Thus, contrary to Applicant's assertions, Anderson teaches all of the claimed method steps set forth in claims 1, 2, 5 - 18, 34, and 35, and the rejection of these claims is hereby maintained.

With regard to the rejections based on the Foss reference, Applicant relies upon the use of the device (receiving an umbilical cord) as distinguishing over the reference. As with the Anderson reference, Examiner notes that it is the claimed structure on which Applicant must rely to define the structure of the apparatus. As such, Applicant's claimed structure remains indistinguishable from Foss. As the structure of Foss is capable of receiving a body portion (cord) it is considered to meet the claimed structure.

Differences based upon intended use that do not result in structural differences cannot serve to distinguish Applicant's claims from Foss. The rejection of claims 19 - 24, 26, and 36, over Foss is hereby maintained.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

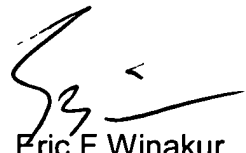
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric F Winakur whose telephone number is 703/308-3940. The examiner can normally be reached on M-Th, 7:30-5; alternate Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 703/308-3130. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Eric F Winakur
Primary Examiner
Art Unit 3736

20 September 2004